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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/254,966	03/16/99	CORREA	R MD-5092/LEA

EXAMINER	
WINKLER,U	
ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/254,966	CORREA ET AL.	
	Examiner	Art Unit	
	Ulrike Winkler, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 13-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 13-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☒ Other: *Seq. Error Report* .

DETAILED ACTION

This Office Action is the response to applicant's amendment filed 9 November 2000. Claims 1-8 and 13-27 are pending and rejected.

The text of those sections of Title 35 U.S.C. not included in this action can be found in a prior office action.

The CRF submitted in response to the Office Action of 18 January 2000 (Paper No. 4) has been reviewed and errors have been detected, please consult the comments in the Sequence Error Report. Appropriate correction is required.

The objection of claim 6 **is maintained** because of the grammar informalities; the claim should read "peptides as defined in claim 1". The amendments filed 9 November 2000 do not alleviate the grammar informality.

The rejection of claims 1-8, and 13-21 under 35 U.S.C. 103(a) as being unpatentable over Zamorano et al. (Virology 1995) and Rodriguez et al. (Arch. Virol. 1994) **is withdrawn** in view of Applicant's arguments.

The rejection of claims 1-8 and 13-23 under 35 U.S.C. 103(a) as being unpatentable over Zamorano et al. (Virology 1995) and Rodriguez et al. (Arch. Virol. 1994) in view of Morgan et al. (Am. J. Vet. Res. 1990) **is withdrawn** in view of Applicant's arguments, which are based on

the lack of reasonable expectation of success due to the problems of efficacy and potency of viral based vaccines.

The rejection of claims 1-8 and 13-27 under 35 U.S.C. 103(a) as being unpatentable over Zamorano et al. (Virology 1995) and Rodriguez et al. (Arch. Virol. 1994) in view of Lubroth et al. (Vaccine 1996) **is withdrawn** in view of Applicant's arguments.

The rejection of claims 24-27 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** in view to Applicant's amendment.

New Grounds of Rejection:

Claims 23-27, as they read on differentiating between infected and vaccinated animals, are rejected under 35 U.S.C. 103(a) as being unpatentable over Rodriguez et al. (Arch. Virol. 1994) and Lubroth et al. (Vaccine 1996).

The instant invention is drawn to differentiating between infected and vaccinated animals based on non-structural proteins.

Rodrigues et al. teaches the ability to differentiate between vaccinated and infected swine based on the animal serum reactivity against peptides from the structural and non-structural regions of FMDV (see abstract and figure 2).

Lubroth et al. teaches the ability to differentiate between vaccinated and infected cattle based on the animal serum reactivity against peptides from the structural and non-structural regions of FMDV (see table 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use peptides against non-structural proteins in assays to distinguish between vaccinated an infected animals. It is known that infected animals can became persistent carriers of FMDV for several years and thus may be a source of new outbreaks (Lubroth et al., column 1). One having ordinary skill in the art would have been motivated to develop an assay that can distinguish vaccinated swine and cattle from those that harbor a persistent infection in order segregate these animals from the uninfected herd. Therefore, the instant invention of using non-structural peptides to distinguish between vaccinated and convalescent animals is obvious over Rodriguez et al. (Arch. Virol. 1994) and Lubroth et al. (Vaccine 1996).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 and 13-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The instant claims are drawn to an FMDV vaccine that is based on peptide

sequences of at least 8 amino acids that correspond to part-sequences from non-structural proteins of FMDV. By definition, the term "vaccine" implies any preparation intended for active immunological prophylaxis; e.g., preparations of killed microbes of virulent strains or living microbes of attenuated (variant or mutant) strains; or microbial, fungal, plant, protozoal, or metazoan derivatives or products. Although just about any protein when inoculated can cause an immune reaction, the prophylactic nature of this reaction is not guaranteed and has to be experimentally determined. Prophylaxis by definition is the prevention of disease or of a process that can lead to disease. This is achieved by use of an antigenic (immunogenic) agent to actively stimulate the immunological mechanism, or the administration of chemicals or drugs to members of a community to reduce the number of carriers of a disease and to prevent others contracting the disease.

The instant specification discloses linear peptide sequences that are reactive with sera from vaccinated (using the standard heat killed vaccine) and infected animals (see specification page 14, lines 23-26). The invention is drawn to a vaccine comprising peptides against the sequence of non-structural proteins. The scope of the claims are not commensurate with the enablement provided by the disclosure with regard to the broad concept of "vaccine" encompassed by the claims. The specification, however, fails to provide sufficient guidance regarding the specific embodiments of the invention to be used as a vaccine with a reasonable expectation of success. Applicant provides serum reactivity with the disclosed peptides as the basis of enabling the vaccine. From the disclosure merely provides experimental results that show the serum of infected animals are reactive to peptides in ELISA based assays (specification page 14, lines 1-8). Reactivity to particular peptides does not give any indication that such

peptides would provide a prophylactic effect to all animals as claimed. Van Lierop et al. (Immunology 1995) summarize that the difficulty of formulating a peptide based vaccine lies in the fact that peptides are presented in the context of the MHC class II molecule and therefore, the response is T-cell specific. This limited presentation would indicate that a peptide may only be effective in a select group of animals that posses the same MHC class II molecules (see table 5). To develop a peptide vaccine that is effective for all animals, the responses to different T-cell epitopes should be tested for all possible MHC haplotypes (p. 84, column 2, last paragraph). In view of the quantity of experimentation necessary, the lack of working examples, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

Claims1-8 and 13-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The instant claims are drawn to an FMDV vaccine that is based on peptide sequences of at least 8 amino acids that correspond to part-sequences from non-structural proteins of FMDV. The specification has shown linear peptides that react with antibodies in the serum from vaccinated and infected animals. Based on the disclosure,the ordinary artisan would not recognize that applicant was in possession of the claimed vaccine. Therefore, the instant invention is rejected.

Potentially Allowable Subject Matter

At this point allowable subject matter can not be clearly indicated, the specific sequences mentioned in the specification could not be searched due to the errors in the raw sequence listing.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ulrike Winkler, Ph.D.

JEFFREY STUCKER
PRIMARY EXAMINER